K070047

MAY 18 2007

COMPANY

Name Nunc A/S, Thermo Fisher Scientific
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DK-4000 Roskilde
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Registration No. 3003150158

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Date of Summary: December 22, 2006

DEVICE

Trade names Nunc IVF PetriDish
Nunc IVF 4-Well Dish
Common name IVF tissue culture dishes
Classification name Assisted reproduction labware, 21 CFR884.6160, Code MQK

Trade Name	Configuration	Catalogue number
Nunc IVF PetriDish	Dish 35x10 mm, with lid	150255
Nunc IVF PetriDish	Dish 60x15 mm, with lid	150270
Nunc IVF PetriDish	Dish 90x17 mm, with lid	150360
Nunc IVF 4-Well Dish	4-Well dish with lid	179830

PREDICATE DEVICE

Trade name Nunc IVF Multidish 4 Well Nunclon
Common name Plastic single use labware dish
Manufacturer Nunc A/S
Catalogue No 144444
510(k) No. K040717

DEVICE DESCRIPTION

The Nunc IVF PetriDishes and the Nunc IVF 4-well Dish are injection molded polystyrene dishes with either a single well or 4 wells and a polystyrene lid.

The single well dishes are available in diameters of 35, 60 and 90 mm.

Both single well and 4-well configurations are made with a clear polystyrene lid.

The polystyrene used for the dishes and lids is a virgin crystal-grade polystyrene, which has successfully passed the USP class VI test for cytotoxicity. The polystyrene is identical with the same Polystyrene use in the predicate device.

For the 4-well configuration, the interface between the dish and the lid is designed with one cut off corner, hence the lid cannot be turned, and therefore cross contamination can be minimized. The dish is designed in such a way that when the lid is mounted on the dish, dishes can be stacked. The lid can be removed with one hand, which eases the use of the plate.

Nunc IVF PetriDishes (Single well dishes), are packed in pouches of x units in a box for a total of Y units, as defined below:

Trade Name	Configuration	Packaging
Nunc IVF PetriDish	Dish 35x10 mm, with lid	10 units in a box for a total of 500 plates
Nunc IVF PetriDish	Dish 60x15 mm, with lid	10 units in a box for a total of 400 plates
Nunc IVF PetriDish	Dish 90x17 mm, with lid	10 units in a box for a total of 150 plates

Nunc IVF 4-well Dishes, are packed in pouches of 4 units in a box for a total of 120 plates.

The Nunc IVF tissue culture dishes are terminally sterilized by gamma irradiation to achieve SAL of 10^{-6}. The dishes are non-pyrogenic as tested by LAL, and nonembryotoxic as tested by one cell mouse embryo assay (MEA).

The Nunc IVF tissue culture dishes are disposable and intended for single use.

INTENDED USE

Preparing, storing, manipulating or transferring human gametes or embryos for in vitro fertilization (IVF) or other in vitro fertilization techniques, and cell culture.

Comparison to predicate device:

	Nunc IVF 4-Well Dish and **Nunc IVF PetriDish, 35x10mm, 60x15mm, 90x17mm**	**Nunc IVF Multidish 4 Well Nunclon**
Intended use	Preparing, storing, manipulating or transferring human gametes or embryos for in vitro fertilization (IVF) or other in vitro fertilization techniques, and cell culture.	Preparing, storing, manipulating or transferring human gametes or embryos for in vitro fertilization (IVF) or other in vitro fertilization techniques, and cell culture.
Indication for use	In vitro fertilization technique, cell culture	In vitro fertilization techniques, cell culture
Contraindication	N/A	N/A
Patient/embryo contact material	Polystyrene surface	Polystyrene surface treated
Design features – IVF 4-Well Dish	The bottom of the plate is optimised flat and optically clear. The lid and the plate have a cut off corner which requires that the lid always has the same orientation; thus cross contamination can be minimized. The lid can be handled by one hand while other lab equipment can be handled by the other hand. The plates can be stacked.	The bottom of the plate is optimised flat and optically clear. The lid and the plate have a cut off corner which requires that the lid always has the same orientation; thus cross contamination can be minimized. The lid can be handled by one hand while other lab equipment can be handled by the other hand. The plates can be stacked.
Design features – IVF PetriDish	N/A	The bottom of the plate is optimised flat and optically clear. The lid and the plate have a cut off corner which requires that the lid always has the same orientation; thus cross contamination can

		be minimized. The lid can be handled by one hand while other lab equipment can be handled by the other hand. The plates can be stacked.
Safety features	N/A	N/A
Other relevant characteristics	▪ Sterile (SAL 10^{-6}) ▪ Tested non-pyrogenic by LAL ▪ Passed 1-cell mouse embryo test	▪ Sterile (SAL 10^{-6}) ▪ Tested non-pyrogenic by LAL ▪ Passed 1-cell mouse embryo test

The Nunc IVF PetriDishes and Nunc IVF 4-Well Dish (hereinafter called Nunc IVF tissue culture dishes) and the predicate device Nunc IVF Multidish 4 Well Nunclon, have similar applications which include cell culture and IVF. Both devices are sterile with SAL of 10^{-6}. They are tested non-pyrogenic by Limulus Amebocyte Lysate (LAL) and nonembryo toxic as tested by the mouse embryo assay (MEA). The plates are made of the same material (Polystyrene), and they are both gamma irradiated.

The differences between the Nunc IVF tissue culture dishes and the Nunc IVF Multidish 4 Well Nunclon is that the Nunc IVF tissue culture dishes have not been surface treated, and the configuration of the single well devices are not identical to the Nunc IVF Multidish 4 Well Nunclon. These differences do not affect the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Jana S. Hellmann
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Kamstrupvej 90
DK-4000 Roskilde
DENMARK

MAY 18 2007

Re: K070047
Trade/Device Name: Nunc IVF Dishes and Nunc IVF 4-Well Dish
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: May 3, 2007
Received: May 7, 2007

Dear Ms. Hellmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070047

Device name: Nunc IVF 4-Well Dishes

Indications For Use:

Nunc IVF 4-Well Dishes are intended for preparing, storing, manipulation or transferring human gametes or embryos for in-vitro fertilization (IVF), or other in vitro fertilization techniques and cell culture.

Prescription Use_X_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070047

Indications for Use

510(k) Number (if known): K070047

Device name: Nunc IVF PetriDishes (35 x 10 mm, 60 x 15 mm and 90 x 17 mm)

Indications For Use:

Nunc IVF PetriDishes are intended for preparing, storing, manipulation or transferring human gametes or embryos for in-vitro fertilization (IVF), or other in vitro fertilization techniques and cell culture.

Prescription Use X
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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